

**UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT**

Barbara Izzarelli,
Plaintiff,

v.

R.J. Reynolds Tobacco Company,
Defendant.

CIVIL ACTION NO.
3:99-cv-2338 (SRU)

**RULING ON MOTION FOR A NEW TRIAL AND
RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW**

Barbara Izzarelli smoked Salem King cigarettes for over twenty-five years until she was diagnosed and treated for larynx cancer at the age of 36. On May 26, 2010, after fourteen days of evidence, a jury determined that R.J. Reynolds Tobacco Company (“R.J. Reynolds”), the manufacturer of Salem King cigarettes, was 58% responsible for Izzarelli’s injuries, under theories of strict liability and negligent design, and that Izzarelli was 42% responsible for her injuries.¹ At the close of Izzarelli’s case, R.J. Reynolds moved for judgment as a matter of law pursuant to Rule 50 of the Federal Rules of Civil Procedure. *See* Motion for Judgment as a Matter of Law (doc. # 406). I reserved ruling on that motion. After judgment entered, R.J. Reynolds timely renewed its motion for judgment as a matter of law and filed, in the alternative, a motion for a new trial pursuant to Rule 59 of the Federal Rules of Civil Procedure. *See* Motion for New Trial (doc. # 482).

In its renewed motion for judgment as a matter of law and motion for a new trial, R.J.

¹ The jury awarded Izzarelli \$325,500 in economic damages, which was reduced by stipulation to \$162,500, and \$13,600,000 in non-economic damages. The compensatory award was reduced by 42% to reflect Izzarelli’s liability. The jury also determined R.J. Reynolds should pay Izzarelli punitive damages. On December 21, 2010, I awarded Izzarelli \$3,970,289.87 in punitive damages, an amount equal to her costs of litigation, and judgment entered in her favor on December 30, 2010 in the amount of \$11,952,539.97. *See* Judgment (doc. # 474). On March 2, 2011, I awarded Izzarelli offer of judgment interest pursuant to Conn. Gen. Stat. § 52-192a and an Amended Judgment in the amount of \$28,079,629.27 issued. *See* Amended Judgment (doc. # 489).

Reynolds argues that the evidence presented at trial is insufficient, as a matter of law, to support the jury's verdict; that I erred in precluding testimony about certain "risk factors" for larynx cancer; that I improperly permitted evidence of so-called "youth marketing;" and that the jury was improperly instructed on Connecticut's product liability law and the law of punitive damages. Those claimed errors, R.J. Reynolds contends, entitle it to judgment as a matter of law or, in the alternative, a new trial. For the reasons that follow, the motion is denied.

I. Factual Background

The product at issue in this case is the Salem King menthol 85 millimeter filter cigarette (hereafter "Salems" or "Salem Kings"). The principal dispute at trial concerned whether R.J. Reynolds designed and manufactured a tobacco product with heightened addictive properties that delivered more carcinogens than necessary. In support of her claims, Izzarelli presented testimonial and documentary evidence showing what R.J. Reynolds understood about the properties of nicotine and addiction; how R.J. Reynolds used its understanding of nicotine and addiction to design Salem Kings; that R.J. Reynolds participated in an industry-wide campaign to discredit warnings about the dangers of cigarettes and nicotine addiction; and that R.J. Reynolds manufactured a cigarette with heightened addictive properties that contained a higher than necessary level of carcinogens. At trial, R.J. Reynolds countered Izzarelli's claims with evidence that the presence of nicotine and carcinogens is inherent to all cigarettes and not unique to Salem Kings, and that no specific defect or ingredient in Salem Kings other than those inherent to all cigarettes could be identified as causing Izzarelli's injuries. R.J. Reynolds also introduced evidence that Izzarelli never attempted to quit smoking, she enjoyed smoking, and that warnings about the dangers of smoking appeared on the product label. The trial record in its entirety

supports a jury reasonably finding the following facts about Salem Kings and Izzarelli's injuries.

A. Salem Kings

R.J. Reynolds has manufactured and sold Salem Kings since 1956. *See* Trial Transcript dated May 17, 2010 at 2453 (testimony of James Figlar, R.J. Reynolds' Vice President of Cigarette Product Design Development) (all citations to the trial transcript are hereafter designated "Trans. at ____"). Salem Kings are menthol cigarettes. The addition of menthol to Salem Kings "reduce[d] the irritation of smoking." Trans. at 1405 (testimony of Dr. Michael Cummings); *see also* Trans. at 1525 ("Menthol is a peculiar class of flavorants that also has a stronger physiological effect in that it gives cooling . . . [t]here are cooling receptors throughout your mouth and your throat, and those receptors are responsive to menthol which gives you that cooling sensation"). Menthol enhances the effect of nicotine by "[m]aking it easier to inhale and deliver the nicotine rapidly into the lungs so it gets to the brain quicker. The faster the drug gets there, the more kick you get from the drug." Trans. at 1416-17. Menthol also had the added benefit of masking the bitter taste of nicotine. For younger or beginning smokers, menthol lessens the undesirable effects of smoking, making it easier to achieve a quicker "kick." *Id.*

When Salem Kings entered the marketplace in 1956, it was the second brand of menthol cigarettes available to consumers; Kool cigarettes, then manufactured by Phillip Morris, was the first menthol brand introduced. Ex. # 47 at 1454. The tobacco blend of Salems differed from that of Kools; Salem Kings had a higher percentage of burley, Turkish, and reconstituted tobacco and a lower percentage of flue-cured tobacco and did not contain tobacco stems. *Id.* at 1457. This blend, R.J. Reynolds claimed, produced a smoother, milder, slower-burning product with a balanced tobacco/menthol taste as compared to Kools. *Id.* By 1963, Salem Kings accounted for

six percent of the market share of 18-24 year-old smokers. *Id.* at 1480. From 1963 to 1973, the tobacco industry saw an increase in cigarette brand variety generally, a move to low-tar brands, and a growth in the use of menthol cigarettes. Ex. 47 at 1504. R.J. Reynolds attributed the increased use of menthol cigarettes to the consumer belief that menthol possessed health benefits. *Id.* Despite the increase in smokers choosing menthol products, R.J. Reynolds was unable to capture the market share of its main competitor, Kool, which had demonstrated strong growth in the 14-17 year-old male market. *Id.*

In the early 1970s, R.J. Reynolds identified several areas of weakness in its Salem King brand. *Id.* First, 47% of Salem smokers were classified as “light” smokers meaning those who smoked 1-15 cigarettes per day. Second, consumption was declining overall due to older smokers leaving the marketplace and increasing concerns about the safety of cigarettes. *Id.* During that same period, R.J. Reynolds expressed a desire to increase its share of the under 18 market. Ex. 51. In its efforts to capture a larger share of its desired market, R.J. Reynolds manipulated the nicotine level of Salem Kings through the use of additives and tobacco selection in order to increase “smoker satisfaction.”

1. *Nicotine Manipulation*

“[A] cigarette is a system for delivery of nicotine to the smoker in attractive, useful form.” Ex. 201. Nicotine in smoke appears in two principal forms – free nicotine and bound nicotine. Trans. at 611. Free nicotine moves through the body’s blood-brain barrier faster and provides the smoker with a higher and more immediate “kick.” Trans. at 611; ex. 201. The greater and faster the kick, the greater the addiction liability.² Trans. at 612. R.J. Reynolds recognized two

² “Addiction liability” is defined as the percentage of people who try the drug and become addicted. The addiction liability of nicotine is roughly 80 – 85 percent. The level of addiction is impacted by genetics, stress level,

important factors concerning nicotine: (1) the form of delivery of nicotine affected whether the nicotine was slowly absorbed by the smoker or rapidly absorbed, thereby delivering a more potent nicotine “kick,” *id.*; and (2) there is an effective dose range of nicotine required to maintain addiction. Trans. at 618.

a. “Free” Nicotine

In the 1972 memorandum entitled “Implications and Activities Arising From Correlation of Smoke pH with Nicotine Impact, Other Smoke Qualities, and Cigarette Sales,” R.J. Reynolds acknowledged that rapid absorption of nicotine by the smoker’s body is linked to the amount of “free” nicotine present in the smoke. Ex. 201 at 4125. R.J. Reynolds’ research revealed a direct correlation between market share and the amount of “free” nicotine in a given cigarette. *Id.* at 4124; *see also* exs. 229, 230. Indeed, by lowering the nicotine and tar in some of its brands, R.J. Reynolds had unwittingly decreased the amount of free nicotine and thereby caused a loss of market share. *See* ex. 201 at 4125. Conversely, its competitors had decreased tar and nicotine levels but increased the smoke pH of some of its brands, causing those competitors to realize a corresponding increase in market share. *Id.* at 4126. R.J. Reynolds attributed the increased market share to the increased free nicotine in its competitor’s products.

R.J. Reynolds identified seven methods for manipulating the nicotine “kick” of a cigarette: “(1) increasing the amount of (strong) burley [tobacco] in the blend, (2) reduction of casing sugar used on the burley and/or blend, (3) use of alkaline additive, usually ammonia compounds, to the blend, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids or add alkaline materials to the smoke, and (7) use of high air dilution

socio-economic status, and age of initiation. *See* Trans. at 587-97.

filter systems.” *Id.* at 4127. Its competitors, R.J. Reynolds noted, manipulated free nicotine by controlling the pH balance of the smoke. *Id.* at 4125. R.J. Reynolds expressed an intention to maintain the basic integrity of its Salem Kings but to match its competitors’ market share. *See ex.* 230 (“Our emphasis should be directed toward free nicotine, while pH would provide us with a measure or tool.”). Salem Kings had a pH level of 6.0-6.2 during the late 1960s and early 1970s. Its main competitor, Kool maintained a pH level of 6.2-6.4. *Id.*; *see also ex.* 215.

R.J. Reynolds did not use pH level manipulation to alter the level of free nicotine, *Trans.* at 758; rather R.J. Reynolds boasted that “it had caught up” to its competitors and that it had done so utilizing other methods to increase the level of “free” nicotine in its products. *Ex.* 215; *Trans.* 771-72. R.J. Reynolds stated that “[w]e’ve caught up to P[hillip] M[orris] with respect to nicotine technology. Our approach has been primarily one of controlling the smoke parameters by blend formulation and denicotinization rather than by addition or transposition of nicotine.” *Ex.* 215. R.J. Reynolds’ memorandum, “Nicotine Delivery and Control,” indicates that it had successfully accomplished nicotine delivery manipulation through blend formulation and methods other than pH manipulation. *Ex.* 222.

With respect to blend formulation, R.J. Reynolds understood that the tobacco blend affected the ultimate nicotine and tar delivery to the smoker. Although nicotine occurs naturally in tobacco, its level varies by plant, stalk position and crop year. *Trans.* at 1528. Notably, R.J. Reynolds discovered that (when altered with fructose alone or a fructose/ammonia gas mixture) the tobacco blend formulation G7 used in its Winston and Salem products increased the amount of nicotine in the cigarette as well as the percentage of nicotine transferred to the smoker. *Ex.* 222 at p. 3215. Denicotinization, the process of extracting the nicotine almost entirely from the tobacco

leaf, is more readily understood in the context of nicotine yield, discussed below. *See* Trans. at 636-37.

Salem King cigarettes also contained sugar and ammonia, components identified by R.J. Reynolds as impacting the level of free nicotine in a cigarette. Ex. 227; Trans. at 787. In fact, R.J. Reynolds recognized that the high amount of sugar in Salems relative to the low level in Kools, correlated to a drop in free nicotine in Salems and an increase in market share of Kools. Ex. 227 (“Thus, the physiological strength of the nicotine in the smoke from a Kool has been higher than that from Salem since 1963, which is the reason Salem sales leveled off and Kool sales began a sharp and sustained increase.”). Sugar also masked the bitterness of and increased the potency of the nicotine. Trans. at 787; ex. 227. Ammonia reinforced the effects of nicotine by increasing its content in the cigarette smoke and allowing it to move more rapidly across the blood-brain barrier. Trans. at 630. The chemical acetaldehyde was also used to cut the harshness of the nicotine and reinforce its effects. Trans. at 1565-66.

b. Nicotine Yield

With respect to the effective dose range of nicotine required to maintain addiction, R.J. Reynolds understood that, although an increase in free nicotine would enhance the addictive property of the cigarette, a decrease in the nicotine yield of the cigarette would increase the number of cigarettes required to meet the addiction demand. Ex. 206; Trans. at 789. R.J. Reynolds recognized that “a given smoker on a given day has a rather fixed per hour and per day requirement for nicotine. Given a cigarette that delivers less nicotine than he desires, the smoker will subconsciously adjust his puff volume and frequency, and smoking frequency, so as to obtain and maintain his per hour and per day requirement for nicotine (or, more likely, will change to a brand

delivering his desired per cigarette level of nicotine.)” Ex. 206; Trans. at 620. The effective daily dosage required to maintain addiction is five to eight milligrams of nicotine per day. Trans. at 557.

As early as 1959, R.J. Reynolds concluded that the nicotine yield should range from 1.5 to 2.0 mg per cigarette. Ex. 205. When introduced to the market in 1956, Salem Kings had a nicotine yield of 3.10 mg per cigarette. Ex. 227. After its 1959 study of effective nicotine yields, the nicotine yield in Salems dropped to 1.80 mg per cigarette and remained in the 1.5 to 2.0 mg range until 1966. Ex. 227. During the years that Izzarelli smoked, Salem Kings were designed to deliver 1.3 milligrams per cigarette of nicotine and 18-19 milligrams per cigarette of tar. Ex. AZ0235; Trans. at 2805-06, 2483. It was no accident that Salem Kings had a nicotine yield of 1.3 mg/cigarette. By maintaining the nicotine yield at that level, Salem Kings could deliver a daily effective dose of nicotine in the 5 – 8 mg per day range but the smoker would have to consume more cigarettes in order to achieve full satisfaction. *See* Trans. at 558, 789-90, 2801, and 2803-06.

The fact that the smoker needed to smoke more cigarettes to achieve full satisfaction had two obvious results. First, the smoker would purchase more cigarettes. Second, the smoker would be exposed to more carcinogens, namely tar. *Id.* “Tar” is the tobacco industry term used to describe all byproducts of smoking the tobacco other than water and nicotine. Trans. at 636. Tar yield is affected by the type of filter used, the type of paper used, how the paper is ventilated, the length and composition of the filter and the cigarette itself, as well as the blend of tobacco used in the cigarette. *Id.* at 2470-72. During the years that Izzarelli smoked, Salem Kings contained approximately 15-19 milligrams of tar; during those years, however, R.J. Reynolds possessed the

capability to reduce the level of tar to “one milligram or less.” *Id.* at 2469; *see also* AZ-8235 (R.J. Reynolds’ others brands had 2 mg of tar in 1973, and Salem Kings delivered a higher level of tar than its chief competitor, Kool.). Because the causal relationship between smoking and cancer is dose-related, Trans. at 854-87, the downward manipulation of the nicotine yield increased the smoker’s exposure to tar and risk of developing cancer.

From the evidence above, the jury could have reasonably found that R.J. Reynolds manipulated and altered the tobacco and the chemical additives in Salem Kings to enhance the addictive nature of the product, increase the number of cigarettes smoked by the consumer, and ultimately deliver a higher level of carcinogens to the consumer as compared to other cigarette products.

B. Izzarelli’s Injuries

Izzarelli began smoking when she was a young teenager and she chose Salem Kings because she heard from friends and advertisements that Salems were milder; the other cigarettes she experimented with were too strong for her. Trans. at 2602-07. Izzarelli quickly became a heavily-addicted smoker who smoked daily two to three packs of Salem Kings. Trans. at 598-99, 867-73, 1087-88, 1326-27, 1347-48, and 3199-201, 3204-05. In 1996, at age 36 and after smoking daily for over 25 years, Izzarelli was diagnosed with stage T-3 squamous cell cancer of the larynx. Trans. at 843, 2012-14. She underwent surgery to remove her larynx, create an opening in her windpipe called a stoma, and position a laryngectomy tube. Trans. at 2027-28. After surgery, Izzarelli received radiation treatment. *Id.* at 2035-36. Izzarelli is cancer-free, but continues to have difficulties with the stoma and laryngectomy tube. *See generally* Trans. at 2038-54, 2081. She quit smoking in January 1997.

Although it is uncommon for a woman in her 30s to develop laryngeal cancer, laryngeal cancer caused by smoking is dose-related; the more a person smokes, the greater the likelihood of developing the condition. *See* Trans. at 2076. Izzarelli smoked 2 to 3 packs a day for 25 years; the equivalent of smoking a pack a day for 30 to 50 years. Trans. at 854-57, 867-73, 2003, 2022-23. Smoking is attributed as the cause of 95% of cancers of the larynx, with the other 5% attributed to toxic exposure. Trans. at 853-54. A person with a pack-a-day history similar to Izzarelli's has between a 6.9 and 20 times greater chance of developing laryngeal cancer than one who does not smoke. *Id.* at 863-64. The heightened addictive properties of Salem Kings and the heightened level of tar they produce, coupled with Izzarelli's heavy smoking, permitted the jury to find that Izzarelli's injuries were a result of smoking Salem Kings.

II. Standards

A. Motion for Judgment as a Matter of Law

Rule 50(b) of the Federal Rules of Civil Procedure provides for the entry of judgment as a matter of law where a jury renders a verdict for which there is no legally sufficient evidentiary basis. A Rule 50 motion may not be granted unless "the evidence is such that, without weighing the credibility of the witnesses or otherwise considering the weight of the evidence, there can be but one conclusion as to the verdict that reasonable persons could have reached." *Densberger v. United Technologies Corp.*, 125 F. Supp. 2d 585, 590 (D. Conn. 2000), *aff'd*, 297 F.3d 66 (2002) (quoting *This Is Me Inc. v. Taylor*, 157 F.3d 139, 142 (2d Cir. 1998)). The court, in deciding a Rule 50 motion, "must give deference to all credibility determinations and reasonable inferences of the jury . . . and it may not itself weigh the credibility of the witnesses or consider the weight of the evidence." *Galdieri-Ambrosini v. Nat'l Realty & Dev. Corp.*, 136 F.3d 276, 289 (2d Cir.

1998). The court shall not substitute its own judgment for that of the jury, rather the motion should be granted only if:

- (1) there is such a complete absence of evidence supporting the verdict that the jury's findings could only have been the result of sheer surmise and conjecture, or
- (2) there is such an overwhelming amount of evidence in favor of the movant that reasonable and fair minded persons could not arrive at a verdict against it.

Galdieri-Ambrosini, 136 F.3d at 28. The test on a Rule 50 motion is not the strength or weakness of the evidence, but whether the evidence presented was such that a “reasonable juror would have been compelled to accept the view of the moving party.” *Densberger*, 125 F. Supp. 2d at 590 (citing *This Is Me Inc.*, 157 F.3d at 142).

B. Motion for New Trial

A motion for a new trial pursuant to Rule 59 of the Federal Rules of Civil Procedure “should not be granted unless the court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice.” *Kosmyinka v. Polaris Indus.*, 462 F.3d 74, 82 (2d Cir. 2006). On a Rule 59(a) motion for a new trial the court may consider the credibility of the witnesses and the weight of the evidence, however, “Rule 59 is not a vehicle for the relitigation of old issues, presenting the case under new theories, securing a rehearing on the merits, or otherwise taking a ‘second bite at the apple.’” *Lawyers Title Insurance Corp. v. Singer*, -- F. Supp. 2d ---, 2011 WL 1870277 (D. Conn. 2011) (quoting *Svege v. Mercedes-Benz Credit Corp.*, No. 3:01cv1771, 2004 WL 2377485 (D. Conn. Sept. 28, 2004)). Rather, the primary grounds for granting a Rule 59 motion turn on “an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.” *Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd.*, 956 F.2d 1245, 1255 (2d Cir. 1992) (citations and internal

quotation marks omitted); *see also* 11 Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice & Procedure Civil 2d* § 2810.1 at 121–28 (1995). “A district court has broad discretion in determining whether to grant a motion to alter or amend the judgment.” *Baker v. Dorfman*, 239 F.3d 415, 427 (2d Cir. 2000) (citing *McCarthy v. Manson*, 714 F.2d 234, 237 (2d Cir. 1983) (per curiam)).

III. Discussion

R.J. Reynolds’ arguments for judgment as a matter of law center on the sufficiency of the evidence presented at trial. Its arguments for a new trial concern certain evidentiary rulings and jury instructions. The principal arguments are addressed in turn.

A. The Evidence Presented at Trial Supports the Jury’s Verdict in Favor of Izzarelli on Her Claims of Strict Liability and Negligence

R.J. Reynolds first argues that Izzarelli failed to present sufficient evidence at trial from which the jury could have found it liable under theories of strict liability and negligence. Specifically, R.J. Reynolds contends that the record lacks evidence that it enhanced or adulterated Salem Kings in a harmful manner as required by Connecticut law and that plaintiff failed to prove that a defect in Salem Kings proximately caused her injuries.³ Accordingly, in R.J. Reynolds’

³ Relying on comment i of section 402A of the Restatement (Second) of Torts and *DuJack v. Brown and Williamson*, 2001 WL 34133836 (Conn. Super. Nov. 13, 2001), R.J. Reynolds maintains that the fact that cigarettes may pose a generic cancer risk is insufficient to recover under the PLA. R.J. Reynolds argued at trial, and argues in the pending motion, that Izzarelli’s claims are essentially run of the mill claims that cigarettes generally are inherently dangerous products. R.J. Reynolds maintains that in order to succeed on her PLA claims, Izzarelli must have come forth with evidence that Salem Kings were harmfully enhanced or altered. The “defects” identified by plaintiff, namely heightened addictiveness and higher than necessary tar yield, R.J. Reynolds claims are merely the inherent risks common to all tobacco products and thus not defects for which recovery is available under the PLA. R.J. Reynolds’ position fails. I held on summary judgment, and hold again today, that Izzarelli demonstrated precisely what the plaintiff in *DuJack* failed to – that Salem Kings cigarettes are uniquely designed and manufactured in a manner that makes the product different from other cigarettes. Additionally, although Connecticut derives its

view, plaintiff failed to prove that Salem King cigarettes are defective and unreasonably dangerous.

In Connecticut, product liability actions are governed by the Connecticut Product Liability Act (“PLA” or “the Act”). Conn. Gen. Stat. § 52-572m et seq. The Act’s principal purpose is to protect people from harm caused by defective and hazardous products. *Vitanza v. Upjohn Co.*, 257 Conn. 365 (2001). Under the PLA, a product liability claim may be asserted in actions brought for personal injury caused by the manufacture, construction, design, formulation, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product. Product liability actions include those based on the theories of strict liability and negligence. Conn. Gen. Stat. § 52-572m et seq.

1. *Strict Liability*

Under the PLA, a manufacturer will be held strictly liable for any injury to a consumer that results from a defect in the product of which the consumer is not aware. *Chairaluce v. Stanley Warner Mgmt.*, 236 F. Supp. 385 (D. Conn. 1964). A plaintiff, in a strict liability action, is not required to prove the existence of a specific defect; the plaintiff need only bring forth evidence of “some unspecified dangerous condition.” *Giglio v. Conn. Light and Power, Co.*, 180 Conn. 230, 234-35 (1980). In order to recover under the doctrine of strict liability, the plaintiff must prove that: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of sale; and (5) the

definition of “unreasonably dangerous” in the PLA from comment i, R.J. Reynolds has come forth with no authority, nor have I found any, that Connecticut has adopted the examples proffered in the Restatement as part of its definition.

product was expected to and did reach the consumer without substantial change in condition. *See Vitanza*, 275 Conn. at 373-74. The questions presented to the jury in this case concerned only the second and third elements.

Connecticut courts define “unreasonably dangerous” in two ways. The first definition, known as the ordinary consumer expectation test, is derived from Comment i of Section 402A of Restatement (Second) of Torts and provides that “the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” *Wagner v. Clark Equip. Co., Inc.*, 243 Conn. 168, 189 (1997). The second definition, commonly referred to as the modified consumer expectation test, was articulated by the Connecticut Supreme Court in *Potter v. Chicago Pneumatic Tools*, 241 Conn. 199 (1997). The modified consumer expectation test sets forth that, where the product at issue is complex, the inquiry turns not on the expectations of the ordinary consumer, but “a balance of the utility of the product’s design with the magnitude of its risks.” *Potter*, 241 Conn. at 220-21.

Generally, the ordinary consumer expectation test is appropriate when the everyday experience of a particular product’s user permits an inference that the product did not meet minimum safety expectations. *Potter*, 241 Conn. at 219-221. Only when this inference cannot be drawn should the factfinder engage in the modified consumer expectation test. *Id.* The modified consumer expectation test, the Connecticut Supreme Court stated, is the appropriate test in cases involving complex product designs. *Id.* Whether the ordinary or modified consumer expectation test applies or both apply in a given situation is left to the discretion of the court. *Id.* at 223; *see discussion infra* section III. C. 1. Here, I determined that the question whether

cigarettes were a complex product was a jury question and accordingly instructed the jurors on both tests.

R.J. Reynolds argued at summary judgment, maintained at trial, and continues to argue that whether Salem Kings are unreasonably dangerous should be measured solely by the ordinary consumer expectation test. It avers that Izzarelli must have demonstrated that Salem cigarettes did not perform as safely as an ordinary consumer would have expected and that Izzarelli failed to identify a specific defect in Salem Kings that could have caused her injuries. On the latter claim, R.J. Reynolds incorrectly states Connecticut law; Izzarelli was required only to submit evidence that Salem Kings, when used as intended, created “some unspecified dangerous condition.” *Giglio*, 180 Conn. at 234-35.

With respect to its claims concerning the ordinary consumer, because ordinary consumers commonly knew the hazardous characteristics of cigarettes long before Izzarelli began smoking in the early 1970s, R.J. Reynolds maintains that the evidence presented at trial failed to show that Salem Kings were more dangerous than the ordinary consumer would expect.⁴ Accordingly, R.J. Reynolds contends, a reasonable jury could only have found from the evidence presented at trial that Salem Kings performed as the ordinary consumer would expect cigarettes to perform and, therefore, the product is not unreasonably dangerous. Even if I agreed with R.J. Reynolds that only the ordinary consumer expectation test applied to this case, which for reasons discussed below in section C. 2. I do not, the record supports the jury finding that Salem King cigarettes did not perform as the ordinary consumer with knowledge common to the community would expect and, therefore, are an unreasonably dangerous product.

⁴ Indeed, Congressionally mandated warning labels have been appearing on cigarettes since 1966, and the post-1969 warnings on cigarettes are deemed sufficient as a matter of law. See *Medtronic Inc. v. Lohr*, 518 U.S. 470, 489 n.9 (1996); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522-31 (1992).

The evidence at trial demonstrated that consumers generally understood cigarettes to contain nicotine and that nicotine naturally occurs in cigarettes. The characteristics at issue, namely the dose and form of the nicotine and the tar level delivered to the consumer by Salems were not, however, naturally occurring components of the cigarette but features that can be and were controlled and manipulated by R.J. Reynolds. The record contained ample evidence that, in an effort to capture market share from Kool, R.J. Reynolds enhanced the natural effect of the nicotine through the use of additives, tobacco formulation, and other methods. *See supra* section I.

Consumers also generally understood and continue to understand that smoking may cause cancer and that cigarettes are addictive. Here, plaintiff presented to the jury evidence that the ordinary consumer of Salem Kings was the beginning smoker who in many cases, like Izzarelli, was a youth or minor smoker, and unaware that the nicotine content of a Salem King had been manipulated. Izzarelli put before the jury evidence that R.J. Reynolds understood the importance of capturing the youth or beginning smoker market in creating a “future consumer” smoking base. Exs. 34, 35. Izzarelli brought forth evidence that R.J. Reynolds actively endeavored to expand Salem Kings’ share of the youth market and that it understood the nicotine level of its main competitor, Kool, to play a role in Kool’s large youth market share. Exs. 34, 47, and 85. The jury heard testimony and considered documentary evidence that R.J. Reynolds understood that minors are unable to fully appreciate the long-term risks of smoking and lack the capacity to make informed choices about smoking. *See* Trans. at 2324-26; and exs. 2A, 81, and 85 at pp. 1-2 (discussing the importance of “influencing pre smokers to try smoking, learn to smoke and become confirmed smokers.”). Plaintiff’s expert, Dr. Neil Grunberg, testified that “[t]he earlier one starts

smoking, for several reasons, more likely one is to develop an addictionSo the person that starts at 11, 12, 13, 14 is more likely to develop a more powerful addiction than the person who starts at 20, 21, 22, 23.” Trans. at 598. R.J. Reynolds actively sought to penetrate the youth market and to sell Salems to new smokers. In order to accomplish the goal, R.J. Reynolds directed marketing campaigns at the youth market and presented its Salem brand as the “cool” or “in” brand. Trans. at 1336-37; and exs. 69, 73, 74 and 591. All the while R.J. Reynolds understood that its target demographic could not appreciate the dangerous and addictive characteristics of a Salem King. *See* ex. 2A.

Putting aside the practice of marketing to youth or beginner smokers and whether the ordinary consumer is a beginning or minor smoker, the jury also heard and considered evidence that, from a time before Izzarelli began smoking Salem Kings through 1994, R.J. Reynolds actively participated in an industry-wide campaign to dispel the notion that cigarettes are an addictive product and to discredit health warnings about cigarettes as “a myth.” *See* Trans. at 2264; exs. 448, 484 (tobacco industry position that whether cigarettes caused disease was an “open debate” or “open controversy”). As one district court previously observed: “[i]t is interesting that in the context of defending this lawsuit defendants contend that the dangerous properties of cigarettes are common knowledge, where [in the not too distant past] they testified in front of Congress that certain claimed dangerous propensities of their products did not exist at all.” *Burton v. RJR Tobacco Co.*, 884 F. Supp. 1515, 1526 (D. Kan. 1995). Other evidence presented at trial demonstrated that consumers have low knowledge and understanding of the health effects of smoking and that Izzarelli, when she began smoking, believed that Salem Kings were milder and that she would not get addicted to them or otherwise be unable to stop smoking. *See* Trans. at

216-13, 2617-18, 2622.

R.J. Reynolds' arguments in its motion for a judgment as a matter of law overlook the evidence presented at trial that the ordinary consumer of Salem Kings did not understand or appreciate that Salem Kings' nicotine content had been manipulated in order to create and sustain addiction. The evidence further supported the claim that R.J. Reynolds intentionally maintained the tar level of Salem Kings at a 15-19 milligrams per cigarette when it could have reduced it to less than 1 milligram per cigarette and thereby reduced substantially the level of carcinogenic exposure for users of Salem Kings.

The jury could have reasonably found from the record that the ordinary consumer for the purposes of this case is the beginning smoker and that the beginning smoker did not fully appreciate the level of manipulation that went into the nicotine and tar ultimately delivered by the product. The evidence presented at trial was also sufficient for the jury to find that ordinary consumers of Salem Kings with knowledge common to the community, whether minors or adults, did not appreciate that the levels of nicotine and tar in Salem Kings were not the naturally occurring levels, but instead that the product was manipulated to be more addictive and carcinogenic than other products. Furthermore, it was reasonable for the jury to conclude that, regardless of the age of the consumer, the ordinary smoking consumer could not fully appreciate the characteristics of Salem Kings because it was not comprised of natural tobacco but a multitude of ingredients designed to alter the form and dose of the nicotine. Accordingly, I do not agree that a reasonable jury considering the evidence would have been compelled to accept R.J. Reynolds' argument that Salem Kings were not unreasonably dangerous under the ordinary consumer expectation test simply because all cigarettes contain nicotine and carcinogens. The jury's

finding that R.J. Reynolds was liable for Izzarelli's injuries under a theory of strict liability is supported by sufficient evidence.

2. *Negligence*

In order to sustain the jury's verdict with respect to her claim for negligence, Izzarelli needed principally to show that the product was in a defective condition. *See Hoetler v. Mohawk*, 170 Conn. 495 (1976); Restatement (Second) of Torts § 402A. The trial evidence was sufficient to support the jury determination that Salem Kings were unreasonably dangerous and that R.J. Reynolds could have made the product less addictive and with fewer carcinogens. Accordingly, R.J. Reynolds is not entitled judgment as a matter of law on Izzarelli's negligence claim.

Lastly, with respect to causation, Izzarelli brought forth evidence that R.J. Reynolds manufactured Salem King cigarettes in a manner that enhanced nicotine delivery in order to make Salem King cigarettes more addictive than other brands, thereby increasing, unnecessarily, the amount of carcinogens delivered to the consumer – defects that caused her to smoke more and develop cancer of the larynx. The jury considered evidence that Salem Kings contained higher than average levels of tar, a carcinogen, and that Salem Kings delivered a nicotine yield of 1.3 mg – a level determined by R.J. Reynolds to be optimal for addiction. The jury also heard testimony that larynx cancer caused by smoking is dose-related. The more a person smokes, the greater the likelihood of developing the condition. Here, Izzarelli smoked 2 to 3 packs a day for 25 years; the equivalent of smoking a pack a day for 30 to 50 years. Although not required under the PLA, Izzarelli also brought forth evidence that R.J. Reynolds could have but did not implement an alternative design that would have reduced the addiction liability of Salem Kings, making it nearly impossible for a smoker to receive the dosage of nicotine linked to addiction. R.J. Reynolds also

had the technology to greatly reduce the level of tar in Salem Kings. The evidence presented at trial was sufficient for the jury to conclude that the heightened addictive properties of Salem Kings contributed to the number of cigarettes smoked by Izzarelli and therefore proximately caused her injuries.

B. Evidentiary Rulings

R.J. Reynolds moves for a new trial on the grounds that I erred in admitting evidence of so-called “youth marketing” and excluding speculative evidence about purported alternative causes of Izzarelli’s cancer. R.J. Reynolds has not identified an intervening change of controlling law or the discovery of new evidence on the issues; instead R.J. Reynolds argues that the evidentiary rulings were legally erroneous and prejudicial.

1. *Youth Marketing Evidence*

R.J. Reynolds claims that I erred by admitting irrelevant evidence of its marketing to minors. Evidence is relevant if the testimony “ha[s] any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 264 (2d Cir. 2002) (alteration in original) (citing *Campbell v. Metro. Prop. & Cas. Ins. Co.*, 239 F.3d 179, 184 (2d Cir. 2001) (quoting Fed. R. Evid. 401)). At the outset, R.J. Reynolds’ characterization of the testimony and documentary evidence concerning its marketing and product development efforts as “youth marketing” is erroneous. The evidence concerned, generally, the considerations that R.J. Reynolds took in designing Salem Kings, the product’s target audience, and how the product was marketed to its target audience. The evidence of product development and marketing was relevant for several purposes.

First, research R.J. Reynolds conducted and utilized in developing its products, including Salem Kings, was relevant to the plaintiff's claims that Salem Kings are not a simple, natural tobacco product, but a complex product, uniquely designed and manufactured to appeal to a beginning smoker like Izzarelli. Because R.J. Reynolds adopted at trial the position that the addictive and cancer-causing properties of Salem Kings were naturally occurring characteristics, evidence to the contrary – namely evidence that R.J. Reynolds endeavored to develop a cigarette to compete with and capture the market share of Kools -- was relevant. As previously set forth, the evidence at trial demonstrated that R.J. Reynolds understood the importance of capturing the youth or beginner smoking market in creating a “future consumer” smoking base. Exs. 34, 35. Testimonial and documentary evidence showed that R.J. Reynolds manipulated its product's ingredients to control its addictive properties in an effort to increase sales. Accordingly, I find no error in permitting the jury to consider evidence that R.J. Reynolds designed its menthol cigarette to be easier to smoke, attractive to the beginning smoker, and to have a precise nicotine delivery level. *See generally* exs. 34, 47, and 85.

Second, in order to demonstrate that Salem Kings were unreasonably dangerous within the meaning of the PLA, evidence of how R.J. Reynolds developed its consumer base and marketed its product to that base was relevant in assessing what the consumer base, i.e., the ordinary consumer, understood about the characteristics of a Salem King. Specifically, in order to meet her burden and show that the ordinary consumer's expectations were not met, Izzarelli offered testimonial and documentary evidence through R.J. Reynolds' designated representative on marketing and advertising. Here, plaintiff presented to the jury evidence that the ordinary consumer was the beginning smoker who, like Izzarelli, was typically a youth or minor smoker and not aware that the

nicotine content of a Salem King had been manipulated. Izzarelli also presented evidence that R.J. Reynolds endeavored to capture the youth or beginning smoking market, exs. 34, 35, and that R.J. Reynolds acknowledged that minors were unable to fully appreciate the long-term risks of smoking and therefore lacked the capacity to make informed choices about smoking. *See* Trans. at 2324-26; exs. 2A, 81, and 85 at p. 2. The jury also considered testimony and documentary evidence that, during the years Izzarelli smoked Salem Kings, R.J. Reynolds actively participated in an industry-wide campaign to discredit claims that cigarettes are an addictive product and to dismiss as a myth the warnings about the adverse health effects of cigarettes. *See* Trans. at 2264; exs. 448, 484 (asserting tobacco industry position that whether cigarettes caused disease was an “open debate” or “open controversy”). Because evidence concerning the demographic that constitutes the ordinary consumer of Salem Kings as well evidence about what such a consumer knew about the product and how that product was presented to the consumer was relevant to Izzarelli’s strict liability claim, I conclude as I did before trial, that the relevance of evidence concerning the marketing of Salem Kings outweighed any prejudice to R.J. Reynolds.

Lastly, evidence concerning product design, decisions made by R.J. Reynolds and how the product was marketed to consumers was also relevant for the purposes of deciding whether to award punitive damages. Connecticut General Statute section 52-240b provides that punitive damages “may be awarded if the claimant proves that the harm suffered was the result of the product seller’s reckless disregard for the safety of product users, consumers or others who were injured by the product.” In evaluating whether R.J. Reynolds evinced a reckless disregard for the safety of the users of Salem King cigarettes, the jury was entitled to consider the product development scheme that led to the creation of the Salem King as a nicotine delivery product that

was intended to increase smoking frequency and thus to expose users to higher levels of carcinogens. I find no error or manifest injustice in the admission of this relevant evidence.

2. *Alternative “Causes” and Risk Factors of Larynx Cancer*

In advance of trial, the parties filed sixteen motions *in limine*. On April 8 and 15, 2010, I conducted a *Daubert* hearing and subsequently granted Izzarelli’s motion, holding that R.J. Reynolds was precluded from presenting evidence regarding speculative theories about the causation of Izzarelli’s larynx cancer. R.J. Reynolds now argues that I erroneously excluded that evidence.

The proponent of expert testimony has the burden of demonstrating by a preponderance of the evidence that the testimony is competent, relevant, and reliable. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 n.10 (1993); *Koppell v. New York State Board of Elections*, 97 F. Supp. 2d 477, 479 (S.D.N.Y. 2000); *Union Bank of Switzerland v. Deutsche Financial Services Corp.*, 2000 WL 178278 at *8 (S.D.N.Y. 2000) (internal citations omitted) (citing *Bourjaily v. United States*, 483 U.S. 171 (1987)). If the expert is deemed competent (otherwise referred to as “qualified”), an issue not in dispute in this case, the trial court must then determine, pursuant to its “gatekeeping” function, whether the proffered expert testimony is “relevant” and “reliable.” *See* Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702 (noting that trial judges have “the responsibility of acting as gatekeepers to exclude unreliable expert testimony”).

Evidence is relevant if the testimony tends to make the existence of any fact that is of consequence to the determination of the action more probable or less probable. *Amorgianos*, 303 F.3d at 264. If the evidence is relevant, the trial court must then determine “whether the proffered

testimony has a sufficiently ‘reliable foundation’ to permit it to be considered” by the trier of fact. *Id.* at 265. Expert testimony may be considered reliable if: (1) “the testimony is based on sufficient facts or data;” (2) the expert’s technique or methodology in reaching the conclusion is considered reliable; and (3) the expert has applied the methodology reliably to the facts of the case. Fed. R. Evid. 702.

During pre-trial proceedings, R.J. Reynolds proffered the testimony of three experts on the issue of causation. Dr. Richard Thomas, a toxicologist, intended to offer expert testimony regarding the epidemiology of laryngeal cancer as it related to Izzarelli and her risk factors for the disease. It was his opinion that it is epidemiologically unlikely that smoking caused Izzarelli’s larynx cancer and that Izzarelli’s sexual history and illegal drug use support an opinion that smoking did not cause or play a contributing role in causing her larynx cancer.

Dr. Sanford Barsky intended to offer testimony concerning the causes and risk factors of laryngeal cancer and that Izzarelli’s age at the time of diagnosis is indicative of a cause other than smoking. He opined that the histology of her cancer does not exclude a viral cause and that the totality of her risk factors point to a non-tobacco cause. Dr. Michael Bertino is an otolaryngologist. He proffered testimony that in light of Izzarelli’s age it cannot be shown that her laryngeal cancer was caused by smoking. All three experts were also expected to testify that the human papillomavirus (“HPV”) could not be ruled out as a possible cause of Izzarelli’s tumor.

R.J. Reynolds intended for its experts to opine that certain alleged risk factors for larynx cancer such as drug use and acid reflux could not be ruled out as the cause of Izzarelli’s cancer. In support of its claim, R.J. Reynolds presented evidence that epidemiological studies demonstrate that no support exists for the proposition that a 36 year-old smoker would develop larynx cancer

from smoking, thus her cancer must have been caused by some agent other than Salem King cigarettes. These other agents, i.e., acid reflux and drug use, R.J. Reynolds argued, are known risk factors associated with larynx cancer, and therefore it ought to be permitted to suggest, through expert testimony, that any one of those factors could be an alternative cause of Izzarelli's cancer. I rejected R.J. Reynolds' argument for several reasons.

First, R.J. Reynolds' reliance on the epidemiology of larynx cancer was not relevant to whether a factor other than smoking specifically caused Izzarelli's disease. Epidemiological studies show only whether a relationship exists between an agent and a disease. *See* Federal Judicial Center, Reference Manual on Scientific Evidence 381-82 (2d ed. 2000). This relationship is characterized as "general causation." *Id.* at 382. Specific causation requires a showing that the agent is not only capable of causing the disease at issue but that it actually caused plaintiff's disease. *Id.* Specific causation cannot be resolved by epidemiology alone. *Id.*

Second, R.J. Reynolds confuses "risk factor" with "cause of disease." A risk factor is "a characteristic statistically associated with, although not necessarily causally related to, an increased risk of morbidity or mortality." *Stedman's Medical Dictionary* (28th ed. 2006). In certain circumstances a risk factor may be causally related to a disease, i.e., smoking is a risk factor for heart disease. Here, however, R.J. Reynolds proffered no evidence that any one of the identified risk factors in this case had a causal relationship with larynx cancer generally or could have caused Izzarelli's cancer specifically. In fact, none of the three experts identified by R.J. Reynolds on the issue of causation could reliably testify that acid reflux, drugs and/or alcohol use was a general, let alone specific, cause of Izzarelli's larynx cancer. *See* doc. # 311 at p. 7-10, exs. F-I; Trans. at 2155-63.

Accordingly, I permitted R.J. Reynolds to present to the jury only evidence concerning scientifically-established causes of larynx cancer and excluded speculative evidence of conditions not scientifically-established to cause larynx cancer generally or to have caused Izzarelli's cancer specifically.

Connecticut courts require that the expert opinion of medical causation be based on more than conjecture and speculation. *See Aspiazu v. Orgera*, 205 Conn. 623, 632 (1987) ("An expert opinion cannot be based on conjecture or surmise but must be 'reasonably probable.' Any expert opinion that describes a 'condition' as possible or merely fifty-fifty is based on pure speculation.") (internal citations omitted). The term "reasonable medical probability" is not specifically defined by the Connecticut courts, but does reflect the requirement that a causal relation exist between the risk factor and the physical condition that is claimed to have resulted from it. That causal relationship can be demonstrated by the direct opinion of a physician, by his deduction from the process of eliminating causes other than the suspected factor, or by his opinion based upon a hypothetical question. *See Bowerman v. United Illuminating*, 1998 WL 910271, *7 (Conn. Super. 1998). Because R.J. Reynolds' experts could not testify that any of the identified risk factors were medically established to be a general cause of larynx cancer, 4/15/2010 Motion in Limine Hrg. Trans. at 21, I find no error in the exclusion of their proffered testimony.

R.J. Reynolds also challenges my limitation on its experts testifying that the human papillomavirus was a specific cause of Izzarelli's larynx cancer. HPV is a virus known to cause cancer of the cervix. *See* Doc. 338 ("Seiden Decl."), Ex. 19, Zoltan Szentirmay, et al., *Human Papillomavirus in Head and Neck Cancer: Molecular Biology and Clinicopathological Correlations*. In recent years medical studies have revealed evidence of a causal association

between HPV and a subset of head and neck cancers. *Id.*; *see also* Seiden Decl., Ex. 21, Ahmad R. Sedaghat, et al., *Prognostic Significance of Human Papillomavirus in Oropharyngeal Squamous Cell Carcinomas* (“Indeed, HPV - particularly type 16 - is detected in up to 70% of oropharyngeal squamous cell carcinomas.”). This causal association also has, on a limited basis, been linked specifically to cancer of the larynx, *see* Seiden Decl., Ex. 12, 90 *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 476 (hereafter “IARC”) (“There is limited evidence in humans for the carcinogenicity of HPV 16 in the larynx . . . there is limited evidence in humans for the carcinogenicity of HPV 6 and HPV 11 in the larynx. . . .”). Generally, there are a number of HPV subtypes considered carcinogenic to humans. These subtypes include 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 66. *See* IARC. HPV 6 and 11 are considered possibly carcinogenic to humans. *Id.* The IARC studies indicate that only HPV 16, 6 and 11 are linked to larynx cancer.

Because HPV is recognized as a possible cause of head and neck cancers it has been suggested that HPV testing play a role in the pathologic assessment of head and neck cancers. *See* Seiden Decl., Ex. 6, Aatur D. Singh and William H. Westra, *Comparison of the Human Papillomavirus In Situ Hybridization and the p16 Immunohistochemistry in the Detection of Human Papillomavirus-Associated Head and Neck Cancer Based on a Prospective Clinical Experience*. Accordingly I permitted the jury to consider testimony and documentary evidence that the human papillomavirus is a general cause of laryngeal cancer.

R.J. Reynolds sought, however, the admission into evidence of the results of a test it claims suggests that Izzarelli’s cancer was caused by HPV. There is no recognized standard test for HPV detection in laryngeal cancer. *Id.* The articles noted above discuss the importance of a standard

for HPV testing and suggest a two-prong test in which a tumor is initially evaluated by p16 immunohistochemistry for the presence of p16 expression. The presence of p16 is considered a surrogate marker for HPV-16. If the tumor shows a positive p16 expression, the tumor is then evaluated by in situ hybridization for the presence of HPV-16. Wide-spectrum HPV in situ hybridization is reserved only for specimens that were p16 positive at the immunohistochemistry testing stage, but HPV-16 negative at the in situ hybridization stage. *Id.*

In January 2008, 3 slides of Izzarelli's squamous cell tumor were submitted for in situ hybridization wide spectrum testing. The wide spectrum testing does not discriminate between HPV types, but tests for the presence of HPV 6, 11, 16, 18, 30, 31, 35, 45, 51, and 52. *See* doc. # 318 ("Ramos Decl."), Ex T. Specifically, the test covered the three HPV strands linked to laryngeal cancer as reported in the IARC study. Izzarelli's tumor did not test positive for HPV. In April 2008, three of Izzarelli's slides were submitted for immunohistochemistry testing. All three slides tested positive for the antibody p16. *See* Ramos Decl., Ex. S. The order in which Izzarelli's tumor slides were tested is obviously reversed from the order suggested in the Singh article, but the method clearly conformed to accepted practices.

Before trial, the parties disputed whether the positive p16 immunohistochemistry test was admissible as evidence in support of R.J. Reynolds' assertion that Izzarelli's larynx cancer was caused by HPV and whether R.J. Reynolds' experts were qualified to testify as such. R.J. Reynolds, as the proponent of expert testimony on the subject of HPV, bore the burden of demonstrating by a preponderance of the evidence, *see Daubert*, 509 U.S. at 592 n.10, that the testimony was competent, relevant, and reliable. R.J. Reynolds argued in the pre-trial motion hearings that, even though the in situ hybridization test was negative for HPV, it should be allowed

to introduce evidence of the positive p16 test as proof that HPV was the alternate cause of Izzarelli's cancer. R.J. Reynolds proffered Dr. Thomas, who was expected to offer the opinion that the positive p16 immunohistochemical test combined with Izzarelli's risk factors for HPV such as her sexual history and illegal drug use support an opinion that smoking did not cause or play a contributing role in causing her larynx cancer.

I held that R.J. Reynolds failed to meet its burden. In light of the negative in situ hybridization test, R.J. Reynolds' experts could not opine that HPV was a specific cause of Izzarelli's cancers. *See generally Gen. Elec. Co. v. Joinder*, 522 U.S. 136, 146 (1997). The fact that Izzarelli's tumor tested positive for a surrogate marker of HPV is entirely irrelevant when the tumor actually tested negative for the HPV itself. Indeed, the record generated by the motions *in limine* made clear that R.J. Reynolds had no intention of proving that HPV caused Izzarelli's injuries and its experts would take the position at trial that the cause of Izzarelli's laryngeal cancer is unknown and that epidemiological studies do not support a finding that smoking caused her cancer. *See doc. # 338 at 4; Ramos Decl., Ex. A, Barsky Rep* ("In summary the pathology in this case does not allow us to determine which of the etiologic agents are at work. While not all causes of laryngeal cancer are known, the totality of the evidence points to a non-tobacco etiology for Mrs. Izzarelli's laryngeal cancer. Although the exact cause has not been conclusively shown, any of her multiple non-smoking risk factors discussed may be the cause, and it cannot be shown epidemiologically or pathologically that Mrs. Izzarelli's laryngeal cancer was caused by or contributed to by cigarette smoking."); *see also Ramos Decl., Ex B. Thomas Rep.* ("although the precise cause of Ms. Izzarelli's laryngeal cancer is unknown . . .").⁵ R.J. Reynolds has not shown

⁵ At trial, R.J. Reynolds also conceded that a more stringent in situ test for HPV was available, but that R.J. Reynolds

that the exclusion of the result of the p16 surrogate marker test was erroneous or clearly prejudicial when actual test results for the virus showed the surrogate to be inaccurate in Izzarelli's case.

C. Jury Instructions

R.J. Reynolds contends that I improperly instructed the jury on the law concerning what constitutes an unreasonably dangerous product in Connecticut, that I should not have instructed the jury on the modified consumer expectation test, and that I failed to properly instruct the jury on the standard for awarding punitive damages. Jury charges are considered as a whole. *Bruneau v. South Kortright Cent. Sch. Dist.*, 163 F.3d 749, 761 (2d Cir. 1988). A jury instruction is considered proper so long as the charge correctly states the law and permits the jury to intelligently decide the questions presented to it. *Id.*

1. *Unreasonably Dangerous*

R.J. Reynolds argues that I failed to adopt R.J. Reynolds' proffered language and therefore improperly charged the jury on the definition of "unreasonably dangerous" as set forth in Comment i of Section 402A of the Restatement (Second) of Torts. The jury was instructed that:

For plaintiff to meet her burden of proving the second element, that Salem King cigarettes are defective, she must show that the Salem King cigarettes were "unreasonably dangerous" to her, the user. . . . **With respect to cigarettes in general, I instruct you that cigarettes are not defective merely because nicotine and/or carcinogenic substances may be inherent in the tobacco from which such cigarettes are manufactured.**

For Barbara Izzarelli to prove that the Salem King cigarettes she smoked were defective or unreasonably dangerous, in one or both of the ways she alleges, she must satisfy at least one of two alternative tests. She must prove either: (1) that the product is unreasonably dangerous to an extent beyond what would be contemplated by the ordinary user, in this case, the cigarette smoker, or (2) that, in light of relevant factors that I will discuss shortly, the benefits of the challenged design do not outweigh the risks of the product.

elected not to submit Izzarelli's tumor to that test. Trans. at 807-08.

Under the first test, which is known as the “ordinary consumer expectation test,” a product may be found defective in design if the product failed to perform as safely as an ordinary user of the defendant’s product, with knowledge common to the community at large, would expect. You must decide what an ordinary user of the defendant’s product reasonably expected and what knowledge was common to the community at large regarding Salem King cigarettes. In determining whether Salem King cigarettes were dangerous to an extent beyond that reasonably expected by the ordinary consumer or user, with the knowledge common to the community, you must focus on the expectations of an ordinary consumer at or near the time Barbara Izzarelli used the product, and the knowledge common to the community in which Barbara Izzarelli lived at or near the time Barbara Izzarelli used the product.

Jury Instructions (doc. # 412) (emphasis added). R.J. Reynolds avers that I improperly rejected its proffered instruction which set forth:

Good tobacco is not unreasonably dangerous merely because smoking can cause cancer or be addictive. Cigarettes are not defective just because they have inherent (or natural) risks and may cause injury. You cannot find against Reynolds on Plaintiff’s product liability claims solely on the basis of the inherently dangerous nature of cigarettes.

Def’s Proposed Inst. 6. This instruction, the defendant claims, properly tracked the language of comment i and therefore comported with Connecticut law. For reasons explained *infra* n. 3, R.J. Reynolds mischaracterizes Connecticut law. Connecticut *derives* its definition of unreasonably dangerous from comment i, it does not incorporate the comment’s examples into the definition nor have I found any case in which a Connecticut court expressly adopts each of the comment’s examples.⁶ Because the instruction proffered by R.J. Reynolds fails to accurately represent the law in Connecticut, there can be no error in declining to give it. *Densberger v. United*

6 Connecticut’s model instruction available at <http://www.jud.ct.gov/JI/Civil/part3/3.10-1.htm> provides the following definition of unreasonably dangerous:

In order to prove that the product was defective, the plaintiff must prove that the condition that is claimed to be a defect made the product unreasonably dangerous. A product is unreasonably dangerous if, at the time of sale, it is defective to an extent beyond that which would be contemplated by the ordinary consumer.

Technologies Corp., 297 F.3d 66, 72-73 (2d Cir. 2002). Moreover, I can identify no meaningful difference between the instruction sought by R.J. Reynolds and the instruction actually given on the lack of defect in cigarettes generally, and R.J. Reynolds has identified no requirement that I adopt verbatim its proposed instruction. *See generally United States v. Han*, 230 F.3d 560, 565 (2d Cir. 2000).

2. *Modified Consumer Expectation Test*

R.J. Reynolds also contends that I erred in instructing the jury on Connecticut's alternative strict liability test known as the modified consumer expectation test. That test, as set forth in *Potter*, is appropriate where the evidence demonstrates that the product is complex. *Potter*, 241 Conn. at 221-23. The modified approach requires that the consumer's expectation be viewed in light of various factors that balance the utility of the product's design with the magnitude of the risks. *Id.* at 221 ("[T]here may be instances involving complex product designs in which an ordinary consumer may not be able to form expectations of safety, in such cases, a consumer's expectations may be viewed in light of various factors that balance the utility of the product's design with the magnitude of its risks."). Under this approach, factors the jury may consider include, but are not limited to: the usefulness of the product, likelihood and severity of the danger posed by the design, feasibility of the alternative design, costs of improved design, ability to reduce danger without impairing usefulness or making the product too expensive, and feasibility of spreading the loss by increasing the product price. *Id.* The modified consumer expectation test does not require plaintiff to present evidence concerning the product's risk and utility.

R.J. Reynolds argues that cigarettes are not a complex product, and even if Salem Kings are complex, the modified consumer expectation test is conflict preempted. On the latter point,

R.J. Reynolds claims that a finding under the modified consumer expectation test that Salem Kings are unreasonably dangerous under the risk versus utility analysis, effectively renders all cigarettes unreasonably dangerous -- creating a dynamic in which a manufacturer can only avoid liability by ceasing the production and sale of cigarettes and resulting in a ban on cigarettes in violation of Congressional policy permitting the sale of tobacco products. *See generally FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (holding that the FDA could not regulate tobacco). R.J. Reynolds overstates the impact of the jury's verdict in this case. The application of the modified consumer expectation test is not conflict preempted because a finding of liability on the basis of the design of Salem cigarettes does not amount to a ban on all cigarettes. The evidence at trial showed that R.J. Reynolds manufactures a number of other tobacco products that do not have the same characteristics as Salem Kings, and the jury's verdict reflects, at most, a finding that, at the time Izzarelli smoked Salems, the nicotine delivery system and tar content of Salem Kings were unreasonably dangerous.

Regarding whether the instruction was appropriate in light of the evidence, as set forth in section I *infra*, the trial record is replete with evidence, including R.J. Reynolds' own cigarette design expert's testimony, that cigarettes are a complex product and that an ordinary consumer may not be able to form proper expectations of safety. Trans. at 1554-55, 2465-66. In Connecticut, when the evidence reveals a dispute about both the complexity of a product's design and the consumer's ability to form expectations about the product's safety, it is permissible for the court to submit to the jury the determination of which test, ordinary or modified, applies. *Potter*, 241 Conn. at 223.

3. *Punitive Damages*

Finally, R.J. Reynolds contends that I failed to instruct the jury that a defendant's reckless conduct for the purposes of punitive damages must be the same conduct that caused plaintiff's harm. Defendant argues that the instruction given was vague and that it "was very likely that the jury based its finding of reckless conduct" on conduct that had, in R.J. Reynolds' view, no effect on Izzarelli. I instructed the jury as follows: "Whether you decide to award punitive damages against the defendant should be based on whether you find that the conduct of R.J. Reynolds giving rise to liability in this case recklessly or wantonly disregarded the safety of consumers or users of Salem King cigarettes." The phrase "giving rise to liability in this case" is, R.J. Reynolds claims, vague and that I should have adopted its proffered wording: "that the specific conduct of defendant giving rise to liability in favor of the plaintiff in this case." Again, R.J. Reynolds is not entitled to an instruction of its precise wording, and I can identify no meaningful difference between the charge proposed by R.J. Reynolds and the one given. Moreover, it bears noting that the charge actually given is far more specific – and defendant-friendly – than the standard punitive damages charge in Connecticut's civil jury instructions, Connecticut Civil Jury Instructions 3.4-4, <http://www.jud.ct.gov/JI/civil/part3/3.4-4.htm> (last visited August 26, 2011), and the punitive damages charge in the leading treatise on federal jury instructions. 4 Leonard B. Sand et al., *Modern Federal Jury Instructions* ¶ 77-01 (Instruction 77-5) (2011).

To the extent that R.J. Reynolds speculates that the jury may have considered conduct that it deems unrelated to Izzarelli's injuries does not render the instruction erroneous. A jury is presumed to follow the court's instructions, absent indications to the contrary. *United States v.*

Cassese, 428 F.3d 92, 102 (2d Cir. 2005), *citing United States v. Joyner*, 201 F.3d 61, 69-70 (2d Cir. 2000). A jury instruction is considered proper so long as the charge correctly states the law and permits the jury to intelligently decide the questions presented to it. *Bruneau*, 163 F.2d at 761. R.J. Reynolds' criticisms of the jury charge provide no basis for relief from the jury's verdict.

IV. Conclusion

R.J. Reynolds' motion for a new trial or for judgment as a matter of law raises a myriad of claims, issues and arguments. Many of the assertions made in support of its motion fail the straight-face test and rely on a wholly inaccurate description of the trial record. Although this ruling does not address every one of R.J. Reynolds' arguments, I have considered them all and find them to be meritless. Accordingly, R.J. Reynolds' motion for judgment as a matter of law, or in the alternative for a new trial, is denied.

It is so ordered.

Dated at Bridgeport, Connecticut, this 26th day of August 2011.

/s/ Stefan R. Underhill
Stefan R. Underhill
United States District Judge